REMARKS

Claims 1-42 were originally filed with the application. Claims 1-26 and 35-42 were canceled, and new Claims 43-45 were added. Claims 31-34 and 43-45 are now under examination and stand rejected by the Examiner.

1. Election/Restriction

The Applicant appreciates the Examiner's acknowledgement of the restriction requirement reply filed on July 17, 2007.

2. Information Disclosure Statement

The Applicant appreciates the Examiner's acknowledgement of the information disclosure statement filed on March 16, 2007 and the supplemental information disclosure statement filed on August 9, 2007. The Applicant also appreciates the Examiner's examination of all references cited on both statements.

3. Sequence Requirement

The Applicant acknowledges the Examiner's request for amendments to be made to the specification and has made such amendments to the specification via substitution of paragraphs (see p. 2). Applicant has also submitted all SEQ IDs in digital format via compact disc and also in paper format in compliance with 37 C.F.R. 1.821(a)(1) and (2). No new matter is associated with the submission of these SEQ IDs.

4. Specification

The Applicant acknowledges the Examiner's objection to the embedded hyperlink in paragraph [0088]. Applicant respectfully directs the Examiner to substitute paragraph [0088] on p. 3 of this response.

5. Rejection of Claims 31-34 and 43-45 under 35 U.S.C. 103(a).

The Examiner has rejected the above listed claims by combining the teachings of the Kuratomi (Eur Arch Otorhinolaryngol, 1999) and Momparler references. (Anti-Cancer Drugs, 1997). The Examiner states that the teachings of Kuratomi show a combination therapy approach to the treatment of

nasopharyngeal cancer (NPC), and that Momparler demonstrates that 5-azacytidine (5-AZA) can be used to treat squamous cell lung cancer, and then alleges that the combination of these two references makes the claimed combination therapy of a demethylating agent plus another anti-cancer therapy to treat NPC obvious.

Applicant would like to first point out that in order for an Examiner to establish a *prima facie* case of obviousness, the Examiner must show that each and every one of the claim limitations was suggested or taught by the prior art being relied upon. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art" (*In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)). Applicant contends that neither of the above combined references (singly or in combination) discloses all of the claims limitations of the invention at hand, which is a combination therapy for NPC using a demethylating agent such as 5-AZA plus another anti-cancer therapy.

It is true that *KSR International Co. v. Teleflex Inc.* (82 USPQ2d 1385 (2007)) has refined the approach taken by the USPTO in examining patents to prevent extreme rigidity in applying the TSM test, but it has not eliminated the TSM test or the time-tested USPTO standards used to determine obviousness. In *KSR* the Supreme Court reaffirmed the framework for determining obviousness as set forth in *Graham v. John Deere Co.*: "[T]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." When considering obviousness of a combination of known elements, the operative question is thus "whether the improvement is more than the predictable use of prior art elements according to their established functions." Applicant contends that the Examiner has not met his burden of showing whether the invention at hand is only a predictable use of prior art elements yielding predictable results. The Examiner is well aware that cancers are not one and the same, that when cancer cells of similar cell-type form tumors in distant locales they behave and evolve and react differently, drug penetration to each region of the body is different, pharmacokinetics of drugs in those regions are different, and cancers develop characteristics of the locales in which they are found. A metastatic lesion of one cancer may not respond to a drug that can kill the primary lesion. In other words, a therapy that works for one cancer may not work for another no matter how similar the cell type. Thus, it is improper scientifically and medically, and is clearly not obvious, for the Examiner to conclude that a treatment that works for lung cancer would be effective in NPC without identifying a teaching in the prior art that would make the Examiner's conclusion predictable.

Additionally, the therapy used in Momparler is 5-AZA monotherapy, not a combination therapy as claimed in the invention. The combination therapy in Kuratomi has absolutely no relation whatsoever to this claimed invention except that it happens to describe a combination therapy in the same cancer model using two separate anti-cancer agents, so Applicant contends that it would not be obvious to read Kuratomi, and then take the teaching from Momparler and apply it to Kuratomi to replace one of the combination agents.

Applicant further contends that one of skill in the art would not have any reasonable expectation that a demethylating agent would work the same as the claimed combination in Kuratomi and it would require significant experimentation to verify that hypothesis. Following the Examiner's line of logic, any combination invention in any patentable field would make all combinations in that field obvious no matter how distantly related the combinations so long as one element of the combination was maintained in both inventions, and that is clearly not in line with patent law nor does Applicant believe the Examiner is intending to suggest such a conclusion.

Furthermore, the Examiner has the burden to prove that the prior art relied upon contains some suggestion or incentive that would motivate the skilled artisan to modify a reference. See *Karsten Mfg. Corp. v. Cleveland Gulf Co.*, 242 F.3d 1376, 1385 (Fed. Cir. 2001). Applicant submits that the Examiner has not satisfied this burden as neither reference discusses or even so much as hints at the combination that is claimed by the inventors.

Finally, the Examiner has the burden of proving that the proposed modification of the prior art has a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. Applicant submits that the Examiner has not satisfied this burden for the reasons stated above, and adds that the Examiner needs to explain without relying on personal inference or opinion why one of skill in the art would infer from the use of 5-AZA in lung cancer that it would be an effective treatment as a combination treatment for NPC.

In view of the foregoing, Applicant submits that the rejection under 35 U.S.C. 103(a) has been overcome and respectfully requests that the rejection be removed and that Claims 31-34 and 43-45 be placed in condition for allowance.

If the Examiner notes any further matters which would be expedited by a telephonic interview, she is requested to contact Dr. Jennifer M. McCallum at the telephone number listed below.

It is believed that no fees are due in this matter; however, if a fee is due the Commissioner is authorized to charge it to deposit account No. 502679.

Respectfully submitted,

3/18/08
Date

By: _____

Jennifer M. McCallum, Ph.D., Esq.
Reg. No. 52,492
The McCallum Law Firm, P.C.
P.O. Box 929
Erie, CO 80516
Phone: 303-828-0655
Fax: 303-828-2938
E-mail: administration@mccallumlaw.net